# PATENT COOPERATION TREATY

From the
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

To:

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# PCT

NOTIFICATION OF TRANSMITTAL OF THE INTERNATIONAL PRELIMINARY EXAMINATION REPORT
(PCT Rule 71.1)

| | |
|---|---|
| Date of mailing *(day/month/year)* | 29.10.2004 |
| Applicant's or agent's file reference | IMPORTANT NOTIFICATION |
| JNR/PG4901 | |

| International application No. | International filing date *(day/month/year)* | Priority date *(day/month/year)* |
|---|---|---|
| PCT/EP 03/08499 | 30.07.2003 | 01.08.2002 |

Applicant
GLAXO GROUP LIMITED et al.

1. The applicant is hereby notified that this International Preliminary Examining Authority transmits herewith the international preliminary examination report and its annexes, if any, established on the international application.

2. A copy of the report and its annexes, if any, is being transmitted to the International Bureau for communication to all the elected Offices.

3. Where required by any of the elected Offices, the International Bureau will prepare an English translation of the report (but not of any annexes) and will transmit such translation to those Offices.

4. **REMINDER**

The applicant must enter the national phase before each elected Office by performing certain acts (filing translations and paying national fees) within 30 months from the priority date (or later in some Offices) (Article 39(1)) (see also the reminder sent by the International Bureau with Form PCT/IB/301).

Where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary examination report. It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned.

For further details on the applicable time limits and requirements of the elected Offices, see Volume II of the PCT Applicant's Guide.

The applicant's attention is drawn to Article 33(5), which provides that the criteria of novelty, inventive step and industrial applicability described in Article 33(2) to (4) merely serve the purposes of international preliminary examination and that "any Contracting State may apply additional or different criteria for the purposes of deciding whether, in that State, the claimed inventions is patentable or not" (see also Article 27(5)). Such additional criteria may relate, for example, to exemptions from patentability, requirements for enabling disclosure, clarity and support for the claims.

Name and mailing address of the international preliminary examining authority:

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Schmidbauer, A
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PATENT COOPERATION TREATY

# PCT

## INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

| Applicant's or agent's file reference<br>JNR/PG4901 | **FOR FURTHER ACTION** | See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416) |
|---|---|---|
| International application No.<br>PCT/EP 03/08499 | International filing date *(day/month/year)*<br>30.07.2003 | Priority date *(day/month/year)*<br>01.08.2002 |
| International Patent Classification (IPC) or both national classification and IPC<br>A61M11/02 | | |
| Applicant<br>GLAXO GROUP LIMITED et al. | | |

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 7 sheets, including this cover sheet.

   ☐ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

   These annexes consist of a total of sheets.

3. This report contains indications relating to the following items:

   - I ☒ Basis of the opinion
   - II ☐ Priority
   - III ☒ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
   - IV ☒ Lack of unity of invention
   - V ☒ Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
   - VI ☐ Certain documents cited
   - VII ☐ Certain defects in the international application
   - VIII ☐ Certain observations on the international application

| Date of submission of the demand | Date of completion of this report |
|---|---|
| 12.02.2004 | 29.10.2004 |
| Name and mailing address of the international preliminary examining authority:<br>European Patent Office<br>D-80298 Munich<br>Tel. +49 89 2399 - 0 Tx: 523656 epmu d<br>Fax: +49 89 2399 - 4465 | Authorized Officer<br>Borowski, A<br>Telephone No. +49 89 2399-2758 |

# INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/EP 03/08499

## I. Basis of the report

1. With regard to the **elements** of the international application *(Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17))*:

**Description, Pages**

1-47 as originally filed

**Claims, Numbers**

1-58 as originally filed

**Drawings, Sheets**

1/12-12/12 as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: , which is:

- ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

- ☐ the description, pages:
- ☐ the claims, Nos.:
- ☐ the drawings, sheets:

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)).

   *(Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)*

6. Additional observations, if necessary:

**III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability**

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:

   ☐ the entire international application,

   ☒ claims Nos. 56-58

   because:

   ☐ the said international application, or the said claims Nos. relate to the following subject matter which does not require an international preliminary examination (specify):

   ☐ the description, claims or drawings *(indicate particular elements below)* or said claims Nos. are so unclear that no meaningful opinion could be formed *(specify)*:

   ☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.

   ☒ no international search report has been established for the said claims Nos. 56-58

2. A meaningful international preliminary examination cannot be carried out due to the failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions:

   ☐ the written form has not been furnished or does not comply with the Standard.

   ☐ the computer readable form has not been furnished or does not comply with the Standard.

**IV. Lack of unity of invention**

1. In response to the invitation to restrict or pay additional fees, the applicant has:

   ☐ restricted the claims.

   ☐ paid additional fees.

   ☐ paid additional fees under protest.

   ☒ neither restricted nor paid additional fees.

2. ☐ This Authority found that the requirement of unity of invention is not complied with and chose, according to Rule 68.1, not to invite the applicant to restrict or pay additional fees.

3. This Authority considers that the requirement of unity of invention in accordance with Rules 13.1, 13.2 and 13.3 is

   ☐ complied with.

☐ not complied with for the following reasons:

4. Consequently, the following parts of the international application were the subject of international preliminary examination in establishing this report:

☐ all parts.

☒ the parts relating to claims Nos. 1-51 .

**V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

1. Statement

| | | | |
|---|---|---|---|
| Novelty (N) | Yes: | Claims | 7-10,14-27,29,38,39,44,46-51 |
| | No: | Claims | 1-6,11-13, 28, 30-37, 40-43, 45 |
| Inventive step (IS) | Yes: | Claims | |
| | No: | Claims | 1-51 |
| Industrial applicability (IA) | Yes: | Claims | 1-51 |
| | No: | Claims | |

2. Citations and explanations

**see separate sheet**

**Re Item III**

**Non-establishment of opinion with regard to novelty, inventive step and industrial applicability**

Claims 56-58 do not meet the requirements of Article 6 PCT in that the matter for which protection is sought is not clearly defined. Said claims contain references to the drawings. According to Rule 6.2(a) PCT, claims should not contain such references except where absolutely necessary, which is not the case here.

**Re Item IV**

**Lack of unity of invention**

IV.1 This International Preliminary Examination Authority considers that there are the following 3 inventions claimed in the international application:

a) the subject-matter of independent claim 1, followed by dependent claims 2 to 51,
b) the subject matter of independent claim 52,
c) the subject matter of independent claim 53, followed by dependent claims 54 and 55.

These 3 inventions are not so linked that they form a single general inventive concept (Rule 13.2 PCT). The single general inventive concept linking the inventions according to different claims can be defined by the common features of these claims. In the present case these common features is a fluid discharge device.

A fluid discharge device, however, is known from the document FR5812826 (=D1; see Figure 1 (10, 20, 30)).

Consequently, the single general concept in the present case is not novel (and hence non inventive) and the application, therefore, does not comply with the requirements of unity of invention (Rule 13.1 PCT).

IV.2 According to the wish of the applicant expressed in his letter dated 26 February 2004, this Authority has established this international preliminary examination report on the

basis of claims 1 to 51.

**Re Item V**

**Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

Reference is made to the following documents:

D1: FR-A-2 812 826 (VALOIS SA) 15 February 2002 (2002-02-15)

D2: US-B1-6 189 739 (VON SCHUCKMANN ALFRED) 20 February 2001 (2001-02-20)

D3: GB-A-2 251 898 (D M W) 22 July 1992 (1992-07-22)

V.1 Independent claim 1 does not meet the requirements for novelty (Article 33(2) PCT), since it reads onto the disclosure of document D1, which is considered to represent the closest prior art for the present application. Document D1 shows a fluid dispensing device (Fig. 8a (50)) comprising a body structure including a housing (Fig. 8a (100)), a nozzle (Fig. 8a (40)) extending out from an upper end of the housing, a fluid discharge device (Fig. 8a (10)) comprising a container (Fig. 8a (10)) having a neck (Fig. 8a (30)) at one end and a compression pump (Fig. 1 and 8a (20)) having a suction inlet located within the container (Fig. 1 (10)) and a discharge outlet (Fig. 1 (21)) extending out from the neck of the container and one lever (Fig. 8a (51)) to apply force to an actuating means (Fig. 8a (55)) used to move the container (Fig. 8a (10)) towards the nozzle (Fig. 8a (40)) so as to actuate the pump (Fig. 8a (20)) wherein the lever is pivotally supported at a lower end within the housing (page 8, lines 15-18) and the actuating means connect to the neck of the container (page 8, line 15-18).

V.2 Dependent claims 2-6, 11-13, 28, 30-37, 40-43 and 45 are also not considered to meet the requirements for novelty (Article 33(2) PCT), since their additional features are also disclosed by document D1.

V.3 Dependent claims 7-10, 14-27, 29, 38, 39, 44 and 46-51 do not contain any features which meet the requirements of the PCT (Article 33(3) PCT) in respect of inventive step. A skilled person would regard it a normal design procedure to combine these features to a device known from D1, see for example:

- pre-load means (claim 29) for assuring a stable jet of atomised liquid: D2,

column 5, lines 31-50;

- aperture in the housing (claim 39) for control of the level of the liquid in the container: D3, page 8, lines 5-10;
- use of a medicament formulation in the form of suspension or solution formulation, or glucocorticoids (claims 46-51) in a fluid dispensing device constitutes part of general knowledge.

V.4 The independent claim 1 should have been drafted in the two-part form, as normally required by Rule 6.3(b) PCT.

V.5 The features of the claims should have been provided with reference signs placed in parentheses (Rule 6.2(b) PCT).